**Sidekick® and Usher® Support Catheters**

**510(k) Summary**
**21 CFR 807.92**

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based is as follows:

**Submitter Information:**

Applicant: Bard Peripheral Vascular, Inc
1625 West 3rd Street
Tempe, Arizona 85281

Phone: 480-638-2939

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Contact: Timothy Wade, Regulatory Affairs Associate

Date March 19, 2013

AUG 0 2 2013

**Subject Device Name:**

| | |
|---|---|
| Device Trade Name: | **Sidekick® and Usher® Support Catheters** |
| Common or Usual Name: | Percutaneous Catheter (21 CFR 870.1250, Product Code DQY) |
| Classification: | Class II |
| Classification Panel: | Cardiovascular |

**Predicate Devices:**

- MicroSheath XL Support Catheter (K073289; cleared January 11, 2008)
- MicroSheath LP Support Catheter (K080849; cleared July 25, 2008)

**Device Description:**

The Sidekick® and Usher® Support Catheters are single lumen catheters with a standard luer fitting hub and separate attachable hemostatic valve. The catheters are recommended to support the Crosser® CTO Recanalization Catheters 14S/14P and S6.

The Sidekick® Support Catheter is available in straight, angled, tapered and non-tapered configurations in 70cm and 110cm effective lengths. The Usher® Catheter is tapered and is available in straight and angled configurations in 83cm and 130cm effective lengths. The Sidekick® and straight Usher® Catheters have a single radiopaque marker 1mm from the distal tip. The angled Usher® Support Catheter configurations have three radiopaque markers at the distal tip for enhanced visualization of the catheter tip and angle under fluoroscopy. The most proximal radiopaque marker is located 15mm from the distal tip.

The product hub identifies SD for Sidekick® Catheter, USH for Usher® Catheter, A for Angled and T for Tapered; in addition to the sheath profile and effective length in centimeters. A guidewire introducer is provided to facilitate the guidewire passage through the optional hemostatic valve. The guidewire introducer shaft color matches the shaft color of the recommended support catheter.

**Indications for Use of Device:**

The Sidekick® and Usher® Support Catheters are single lumen catheters intended to create a pathway for other devices in the peripheral vasculature.

**Contraindications:**

The Sidekick® and Usher® Catheters are contraindicated for use with cutting/scoring balloons, pediatrics, neonatal and neurovascular patients.

**Technological Comparison to Predicate Devices:**

The Sidekick® and Usher® Support Catheters have the following similarities to the predicate devices:

- Same intended use (MicroSheath® XL Predicate)
- Same indications for use (MicroSheath® XL Predicate)
- Same target population (MicroSheath® XL Predicate)
- Same fundamental scientific technology (both predicates)
- Same operating principle (both predicates)
- Same sterility assurance level and method of sterilization (both predicates)

The Sidekick® and Usher® Support Catheters differ from the predicate devices in dimensional characteristics, tapered catheter configurations, modifications in the shaft design, and new materials including the new hemostasis valve and guidewire introducer components. Additionally, as compared to the MicroSheath® LP Support Catheter predicate, the subject Usher® Support Catheter is not indicated for use in the coronary vasculature. The use of the Usher® Support Catheter in the peripheral vasculature is fully within the scope of both predicate devices and therefore does not affect the safety or effectiveness when used as indicated.

**Performance Data:**

To demonstrate substantial equivalence of the subject devices, the Sidekick® and Usher® Support Catheters, to the predicate devices, the technological characteristics and performance criterion were evaluated. Using FDA Guidance Documents on non-clinical testing of medical devices and internal Risk Assessment procedures, the following *in vitro* tests were performed:

- Ablation Efficiency
- Catheter Burst
- Catheter Leak
- Catheter Inner Diameter
- Catheter Outside Diameter
- Catheter Effective Length
- Catheter Hub Testing
- Hub Leak Testing
- Hub Luer Taper
- Kink Resistance
- Track Without Damage
- Tensile Strength
- Delivery of Recommended Devices
- Tracking Force
- Catheter Tip Visualization
- Ease of Guidewire Loading
- Particulate Evaluation
- Coating Integrity
- Pouch Visual Inspection
- Dye Penetration

- Pouch Tensile

Product will have a viable shelf life based upon successful completion of testing performed in accordance with ASTM F1980-07, "Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices", FDA Guidance, "Shelf Life of Medical Devices", issued April 1991, and the Bard internal stability program. Additionally, biocompatibility tests were performed in accordance with ISO 10993-1:2009, "Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process." Testing conducted includes Cytotoxicity, Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity, Pyrogen Testing, Hemolysis, Complement Activation, and *in-vivo* Thrombogenicity.

The results from these tests demonstrate that the technological characteristics and performance criteria of the Sidekick® and Usher® Support Catheters are comparable to the predicate devices and performs at least as safely and effectively as the legally marketed device.

**Conclusions:**

The Sidekick® and Usher® Support Catheters, met all the predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The Sidekick® and Usher® Support Catheters are substantially equivalent to the legally marketed predicate devices, the MicroSheath® XL and MicroSheath® LP Support Catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 2, 2013

Bard Peripheral Vascular, Inc.
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K131493
Trade/Device Name: Sidekick® and Usher® Support Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II
Product Code: DQY
Dated: July 18, 2013
Received: July 19, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

# Indications for Use

510(k) Number (if known):

Device Name: Sidekick® and Usher® Support Catheter

Indications for Use: The Sidekick® and Usher® Support Catheters are single lumen catheters intended to create a pathway for other devices in the peripheral vasculature.

Prescription Use_X_ AND/OR Over-The-Counter Use_____
(Part21 CFR 801 Subpart D) (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kenneth J. Cavanaugh -S